

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

1. – 135. (Cancelled)

136. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a D50 particle size of less than 500 nm and at least one surface stabilizer;
- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
  - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
  - (ii) a 90% Confidence Interval for C<sub>max</sub>, which is between 0.80 and 1.25.

137. (Cancelled)

138. (Cancelled)

139. (Cancelled)

140. (Currently Amended) The method of claim 136, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

141. (Currently Amended) The method of claim 136, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

142. (Previously presented) The method of claim 141, wherein the composition is a single daily dose.

143. (Currently Amended) The method of claim 136, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

144. (Previously presented) The method of claim 143, wherein the composition is a single daily dose.

145. (Currently Amended) The method of claim 136, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

146. (Previously Presented) The method of claim 136, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 µg/mL.h.

147. (Previously Presented) The method of claim 136, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

148. (Currently Amended) The method of claim 136, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or

a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and less than 25% of the  $T_{\max}$  exhibited by micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

149. (Currently Amended) The method of claim 136, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

150. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 145 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC.

151. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 48 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

152. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

153. (Currently Amended) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

154. (Currently Amended) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

155. (Currently Amended) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

156. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-

methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

157. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

158. (Currently Amended) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

159. (Previously presented) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

160. (Currently Amended) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

161. (Currently Amended) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed

human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

162. (Currently Amended) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

163. (Currently Amended) The method of claim 136, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

164. (Currently Amended) The method of claim 136, wherein the D50 particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof are selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

165. (Currently Amended) The method of claim 136, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of less than 500 nm.

166. (Currently Amended) The method of claim 136, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of less than 350 nm.

167. (Currently Amended) The method of claim 136, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 100 nm.

168. (Previously presented) The method of claim 136, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

169. (Previously presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

170. (Previously presented) The method of claim 169, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

171. (Previously Presented) The method of claim 170, wherein the composition is formulated into a tablet dosage form.

172. (Previously Presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

173. (Previously Presented) The method of claim 136, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

174. (Previously Presented) The method of claim 136, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M,

and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

175. (Previously Presented) The method of claim 136, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

176. (Previously Presented) The method of claim 136, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

177. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

178. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;
- (b) within about 10 minutes at least 80% of the composition is dissolved; and
- (c) within about 20 minutes at least 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.



179. (Currently Amended) The method of claim 136, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size of less than 500 nm.

180. (Currently Amended) The method of claim 179, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

181. (Currently Amended) The method of claim 136, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size of less than 500 nm.

182. (Currently Amended) The method of claim 181, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

183. (Previously presented) The method of claim 136, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

184. (Previously presented) The method of claim 136, wherein the subject is a human.

185. (Cancelled)

186. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

187. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

188. (Previously presented) The method of claim 136, wherein the method is used to decrease the risk of pancreatitis.

189. (Previously presented) The method of claim 136, wherein the method is used to treat indications where lipid regulating agents are typically used.

190. (Previously Presented) The method of claim 136, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.

191. (Previously Presented) The method of claim 136, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

192. (Previously Presented) The method of claim 136, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-

methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quaternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-

naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyltrimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

193. (Previously presented) The method of claim 136, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

194. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a mean particle size of less than 500 nm and at least one surface stabilizer;
- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and

(c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:

- (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
- (ii) a 90% Confidence Interval for  $C_{max}$ , which is between 0.80 and 1.25.

195. (Currently Amended) The method of claim 194, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

196. (Currently Amended) The method of claim 194, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

197. (Previously Presented) The method of claim 196, wherein the composition is a single daily dose.

198. (Currently Amended) The method of claim 194, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

199. (Previously Presented) The method of claim 198, wherein the composition is a single daily dose.

200. (Currently Amended) The method of claim 194, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

201. (Previously Presented) The method of claim 194, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139  $\mu\text{g/mL.h}$ .

202. (Previously Presented) The method of claim 194, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

203. (Currently Amended) The method of claim 194, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and less than 25% of the  $T_{\max}$  exhibited by micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

204. (Currently Amended) The method of claim 194, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

205. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 145 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

206. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 48 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

207. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

208. (Currently Amended) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

209. (Currently Amended) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

210. (Currently Amended) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

211. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

212. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

213. (Currently Amended) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

214. (Previously Presented) The method of claim 212, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

215. (Currently Amended) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl)



phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

216. (Currently Amended) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

217. (Currently Amended) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

218. (Currently Amended) The method of claim 194, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, and an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

219. (Currently Amended) The method of claim 194, wherein the mean particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

220. (Currently Amended) The method of claim 194, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of less than 500 nm.

221. (Currently Amended) The method of claim 194, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of less than 350 nm.

222. (Currently Amended) The method of claim 194, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 100 nm.

223. (Previously Presented) The method of claim 194, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

224. (Previously Presented) The method of claim 194, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

225. (Previously Presented) The method of claim 224, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

226. (Previously Presented) The method of claim 225, wherein the composition is formulated into a tablet dosage form.

227. (Previously Presented) The method of claim 194, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

228. (Previously Presented) The method of claim 194, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

229. (Previously Presented) The method of claim 194, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

230. (Previously Presented) The method of claim 194, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

231. (Previously Presented) The method of claim 194, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

232. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

233. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;

(b) within about 10 minutes at least 80% of the composition is dissolved; and  
(c) within about 20 minutes at least 100% of the composition is dissolved,  
wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

234. (Currently Amended) The method of claim 194, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 500 nm.

235. (Currently Amended) The method of claim 234, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

236. (Currently Amended) The method of claim 194, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 500 nm.

237. (Currently Amended) The method of claim 236, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size selected from the group consisting of less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

238. (Previously Presented) The method of claim 194, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

239. (Previously Presented) The method of claim 194, wherein the subject is a human.
240. (Cancelled)
241. (Previously Presented) The method of claim 194, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.
242. (Previously Presented) The method of claim 194, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.
243. (Previously Presented) The method of claim 194, wherein the method is used to decrease the risk of pancreatitis.
244. (Previously Presented) The method of claim 194, wherein the method is used to treat indications where lipid regulating agents are typically used.
245. (Previously Presented) The method of claim 194, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.
246. (Previously Presented) The method of claim 194, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.
247. (Previously Presented) The method of claim 194, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose

calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-nonyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl

ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

248. (Previously Presented) The method of claim 194, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

249. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a D90 particle size of less than 700 nm and at least one surface stabilizer;
- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
  - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
  - (ii) a 90% Confidence Interval for C<sub>max</sub>, which is between 0.80 and 1.25.

250. (Currently Amended) The method of claim 249, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

251. (Currently Amended) The method of claim 249, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

252. (Previously Presented) The method of claim 251, wherein the composition is a single daily dose.

253. (Currently Amended) The method of claim 249, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

254. (Previously Presented) The method of claim 253, wherein the composition is a single daily dose.

255. (Currently Amended) The method of claim 249, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl



ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

256. (Previously Presented) The method of claim 249, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139  $\mu\text{g/mL.h}$ .

257. (Previously Presented) The method of claim 249, wherein the composition exhibits a  $T_{\text{max}}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

258. (Currently Amended) The method of claim 249, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\text{max}}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and less than 25% of the  $T_{\text{max}}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

259. (Currently Amended) The method of claim 249, wherein the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;

- (c) about 200 to about 225 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

260. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

261. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

262. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

263. (Currently Amended) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

264. (Currently Amended) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

265. (Currently Amended) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

266. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

267. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

268. (Currently Amended) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

269. (Previously Presented) The method of claim 267, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

270. (Currently Amended) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

271. (Currently Amended) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

272. (Currently Amended) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

273. (Currently Amended) The method of claim 249, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

274. (Currently Amended) The method of claim 249, wherein the D90 particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

275. (Currently Amended) The method of claim 249, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of less than 500 nm.

276. (Currently Amended) The method of claim 249, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of less than 350 nm.

277. (Currently Amended) The method of claim 249, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 100 nm.

278. (Previously Presented) The method of claim 249, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

279. (Previously Presented) The method of claim 249, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

280. (Previously Presented) The method of claim 279, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

281. (Previously Presented) The method of claim 280, wherein the composition is formulated into a tablet dosage form.

282. (Previously Presented) The method of claim 249, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

283. (Previously Presented) The method of claim 249, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

284. (Previously Presented) The method of claim 249, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

285. (Previously Presented) The method of claim 249, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

286. (Previously Presented) The method of claim 249, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium

lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

287. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

288. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;
- (b) within about 10 minutes at least 80% of the composition is dissolved; and
- (c) within about 20 minutes at least 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

289. (Currently Amended) The method of claim 249, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size of less than 700 nm.

290. (Currently Amended) The method of claim 289, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size selected from the group consisting of less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

291. (Currently Amended) The method of claim 249, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-

chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size of less than 700 nm.

292. (Currently Amended) The method of claim 291, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size selected from the group consisting of less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

293. (Previously Presented) The method of claim 249, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

294. (Previously Presented) The method of claim 249, wherein the subject is a human.

295. (Cancelled)

296. (Previously Presented) The method of claim 249, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

297. (Previously Presented) The method of claim 249, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

298. (Previously Presented) The method of claim 249, wherein the method is used to decrease the risk of pancreatitis.

299. (Previously Presented) The method of claim 249, wherein the method is used to treat indications where lipid regulating agents are typically used.

300. (Previously Presented) The method of claim 249, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.



301. (Previously Presented) The method of claim 249, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

302. (Previously Presented) The method of claim 249, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate

dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quaternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium

salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

303. (Previously Presented) The method of claim 249, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

304. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a D50 particle size of about 500 nm and at least one surface stabilizer;
- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
  - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
  - (ii) a 90% Confidence Interval for C<sub>max</sub>, which is between 0.80 and 1.25.

305. (Currently Amended) The method of claim 304, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

306. (Currently Amended) The method of claim 304, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

307. (Previously Presented) The method of claim 306, wherein the composition is a single daily dose.

308. (Currently Amended) The method of claim 304, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

309. (Previously Presented) The method of claim 308, wherein the composition is a single daily dose.

310. (Currently Amended) The method of claim 304, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

311. (Previously Presented) The method of claim 304, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 µg/mL.h.

312. (Previously Presented) The method of claim 304, wherein the composition exhibits a T<sub>max</sub> after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

313. (Currently Amended) The method of claim 304, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a T<sub>max</sub> selected from the group

consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{\max}$  exhibited by micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

314. (Currently Amended) The method of claim 304, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

315. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 145 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC.

316. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 48 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and

(b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC.

317. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

318. (Currently Amended) The method of claim 317, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

319. (Currently Amended) The method of claim 317, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

320. (Currently Amended) The method of claim 317, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

321. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

(a) 1.0 mg/mL at one hour;

- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

322. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

323. (Currently Amended) The method of claim 322, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

324. (Previously Presented) The method of claim 322, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

325. (Currently Amended) The method of claim 322, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

326. (Currently Amended) The method of claim 322, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

327. (Currently Amended) The method of claim 304, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-

methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

328. (Currently Amended) The method of claim 304, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

329. (Currently Amended) The method of claim 304, wherein the D50 particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof are selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

330. (Currently Amended) The method of claim 304, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of about 500 nm.

331. (Currently Amended) The method of claim 304, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of about 350 nm.

332. (Currently Amended) The method of claim 304, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of about 100 nm.



333. (Previously Presented) The method of claim 304, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.
334. (Previously Presented) The method of claim 304, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.
335. (Previously Presented) The method of claim 334, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.
336. (Previously Presented) The method of claim 335, wherein the composition is formulated into a tablet dosage form.
337. (Previously Presented) The method of claim 304, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.
338. (Previously Presented) The method of claim 304, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.
339. (Previously Presented) The method of claim 304, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.
340. (Previously Presented) The method of claim 304, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is

dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

341. (Previously Presented) The method of claim 304, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

342. (Previously Presented) The method of claim 304, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

343. (Previously Presented) The method of claim 304, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

344. (Currently Amended) The method of claim 304, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size of about 500 nm.

345. (Currently Amended) The method of claim 344, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

346. (Currently Amended) The method of claim 304, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size of about 500 nm.

347. (Currently Amended) The method of claim 346, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D50 particle size selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

348. (Previously Presented) The method of claim 304, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

349. (Previously Presented) The method of claim 304, wherein the subject is a human.

350. (Previously Presented) The method of claim 304, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

351. (Previously Presented) The method of claim 304, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

352. (Previously Presented) The method of claim 304, wherein the method is used to decrease the risk of pancreatitis.

353. (Previously Presented) The method of claim 304, wherein the method is used to treat indications where lipid regulating agents are typically used.

354. (Previously Presented) The method of claim 304, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.

355. (Previously Presented) The method of claim 304, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

356. (Previously Presented) The method of claim 304, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-

cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyl dimethylammonium halogenides, tricetyl

methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

357. (Previously Presented) The method of claim 304, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

358. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a mean particle size of about 500 nm and at least one surface stabilizer;
- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
  - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
  - (ii) a 90% Confidence Interval for  $C_{max}$ , which is between 0.80 and 1.25.

359. (Currently Amended) The method of claim 358, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

360. (Currently Amended) The method of claim 358, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

361. (Previously Presented) The method of claim 360, wherein the composition is a single daily dose.

362. (Currently Amended) The method of claim 358, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

363. (Previously Presented) The method of claim 362, wherein the composition is a single daily dose.

364. (Currently Amended) The method of claim 358, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

365. (Previously Presented) The method of claim 358, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 µg/mL.h.

366. (Previously Presented) The method of claim 358, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

367. (Currently Amended) The method of claim 358, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

368. (Currently Amended) The method of claim 358, wherein the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

369. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is



established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC.

370. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC.

371. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

372. (Currently Amended) The method of claim 371, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

373. (Currently Amended) The method of claim 371, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

374. (Currently Amended) The method of claim 371, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

375. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

376. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

377. (Currently Amended) The method of claim 376, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

378. (Previously Presented) The method of claim 376, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

379. (Currently Amended) The method of claim 376, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

380. (Currently Amended) The method of claim 376, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl)

phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

381. (Currently Amended) The method of claim 358, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

382. (Currently Amended) The method of claim 358, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase and mixtures thereof.

383. (Currently Amended) The method of claim 358, wherein the mean particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

384. (Currently Amended) The method of claim 358, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of about 500 nm.

385. (Currently Amended) The method of claim 358, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of about 350 nm.

386. (Currently Amended) The method of claim 358, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of less than 100 nm.

387. (Previously Presented) The method of claim 358, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

388. (Previously Presented) The method of claim 358, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

389. (Previously Presented) The method of claim 388, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

390. (Previously Presented) The method of claim 389, wherein the composition is formulated into a tablet dosage form.

391. (Previously Presented) The method of claim 358, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

392. (Previously Presented) The method of claim 358, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

393. (Previously Presented) The method of claim 358, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

394. (Previously Presented) The method of claim 358, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

395. (Previously Presented) The method of claim 358, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

396. (Previously Presented) The method of claim 358, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

397. (Previously Presented) The method of claim 358, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

398. (Currently Amended) The method of claim 358, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of about 500 nm.

399. (Currently Amended) The method of claim 398, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

400. (Currently Amended) The method of claim 358, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of about 500 nm.

401. (Currently Amended) The method of claim 400, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size selected from the group consisting of about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

402. (Previously Presented) The method of claim 358, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

403. (Previously Presented) The method of claim 358, wherein the subject is a human.

404. (Previously Presented) The method of claim 358, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.
405. (Previously Presented) The method of claim 358, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.
406. (Previously Presented) The method of claim 358, wherein the method is used to decrease the risk of pancreatitis.
407. (Previously Presented) The method of claim 358, wherein the method is used to treat indications where lipid regulating agents are typically used.
408. (Previously Presented) The method of claim 358, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.
409. (Previously Presented) The method of claim 358, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.
410. (Previously Presented) The method of claim 358, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-

(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-nonyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-



dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

411. (Previously Presented) The method of claim 358, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

412. (Currently Amended) A method of treating a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, peripheral vascular disease, symptomatic carotid artery disease, mixed dyslipidemia, and increased risk of pancreatitis comprising administering to a subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of ~~feno-fibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof having a D90 particle size of about 700 nm and at least one surface stabilizer;

- (b) the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
  - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
  - (ii) a 90% Confidence Interval for C<sub>max</sub>, which is between 0.80 and 1.25.

413. (Currently Amended) The method of claim 412, wherein the composition is bioequivalent to a micronized 54 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

414. (Currently Amended) The method of claim 412, wherein the composition is bioequivalent to a micronized 160 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

415. (Previously Presented) The method of claim 414, wherein the composition is a single daily dose.

416. (Currently Amended) The method of claim 412, wherein the composition is bioequivalent to a micronized 200 mg ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof oral solid dosage form.

417. (Previously Presented) The method of claim 416, wherein the composition is a single daily dose.

418. (Currently Amended) The method of claim 412, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

419. (Previously Presented) The method of claim 412, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139  $\mu\text{g/mL.h}$ .

420. (Previously Presented) The method of claim 412, wherein the composition exhibits a  $T_{\text{max}}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

421. (Currently Amended) The method of claim 412, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\text{max}}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{\text{max}}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

422. (Currently Amended) The method of claim 412, wherein the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof per kg of composition.

423. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 145 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

424. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 48 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

425. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

426. (Currently Amended) The method of claim 425, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

427. (Currently Amended) The method of claim 425, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

428. (Currently Amended) The method of claim 425, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

429. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

430. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

431. (Currently Amended) The method of claim 430, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

432. (Previously Presented) The method of claim 430, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

433. (Currently Amended) The method of claim 430, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

434. (Currently Amended) The method of claim 430, wherein following administration of the composition comprising a dosage of about 160 mg of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

435. (Currently Amended) The method of claim 412, wherein the composition comprises a dosage of about 160 mg of particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

436. (Currently Amended) The method of claim 412, wherein the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

437. (Currently Amended) The method of claim 412, wherein the D90 particle size of the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof is selected from the group consisting of about 600 nm, about 500 nm, about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

438. (Currently Amended) The method of claim 412, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>99</sub> of about 500 nm.

439. (Currently Amended) The method of claim 412, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D<sub>50</sub> of about 350 nm.

440. (Currently Amended) The method of claim 412, wherein the particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a mean particle size of about 100 nm.

441. (Previously Presented) The method of claim 412, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

442. (Previously Presented) The method of claim 412, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

443. (Previously Presented) The method of claim 442, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

444. (Previously Presented) The method of claim 443, wherein the composition is formulated into a tablet dosage form.

445. (Previously Presented) The method of claim 412, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

446. (Previously Presented) The method of claim 412, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

447. (Previously Presented) The method of claim 412, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

448. (Previously Presented) The method of claim 412, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

449. (Previously Presented) The method of claim 412, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

450. (Previously Presented) The method of claim 412, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,



wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

451. (Previously Presented) The method of claim 412, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

452. (Currently Amended) The method of claim 412, wherein upon administration, the composition redisperses such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size of about 700 nm.

453. (Currently Amended) The method of claim 452, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size selected from the group consisting of about 600 nm, about 500 nm, about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

454. (Currently Amended) The method of claim 412, wherein the composition redisperses in a biorelevant media such that the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size of about 700 nm.

455. (Currently Amended) The method of claim 454, wherein the redispersed particles of ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof have a D90 particle size selected from the group consisting of about 600 nm,

about 500 nm, about 400 nm, about 300 nm, about 250 nm, about 200 nm, about 150 nm, about 100 nm, about 75 nm, and about 50 nm.

456. (Previously Presented) The method of claim 412, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

457. (Previously Presented) The method of claim 412, wherein the subject is a human.

458. (Previously Presented) The method of claim 412, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

459. (Previously Presented) The method of claim 412, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

460. (Previously Presented) The method of claim 412, wherein the method is used to decrease the risk of pancreatitis.

461. (Previously Presented) The method of claim 412, wherein the method is used to treat indications where lipid regulating agents are typically used.

462. (Previously Presented) The method of claim 412, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.

463. (Previously Presented) The method of claim 412, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

464. (Previously Presented) The method of claim 412, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol,

cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl

hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

465. (Previously Presented) The method of claim 412, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

466. (Currently Amended) The method of claim 136, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl

ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

467. (Previously Presented) The method of claim 136, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

468. (Currently Amended) The method of claim 136, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{\max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

469. (Previously Presented) The method of claim 136, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

470. (Previously Presented) The method of claim 136, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

471. (Previously Presented) The method of claim 136, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

472. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

473. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

474. (Currently Amended) The method of claim 194, wherein the difference in AUC of the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

475. (Previously Presented) The method of claim 194, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of

about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

476. (Currently Amended) The method of claim 194, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{\max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

477. (Previously Presented) The method of claim 194, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

478. (Previously Presented) The method of claim 194, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

479. (Previously Presented) The method of claim 194, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

480. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

481. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

482. (Currently Amended) The method of claim 249, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, less about 10%, about 5%, and about 3%.

483. (Previously Presented) The method of claim 249, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

484. (Currently Amended) The method of claim 249, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or



a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fene~~fibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{\max}$  exhibited by micronized ~~fene~~fibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

485. (Previously Presented) The method of claim 249, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

486. (Previously Presented) The method of claim 249, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

487. (Previously Presented) The method of claim 249, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

488. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

489. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

490. (Currently Amended) The method of claim 136, wherein the difference in AUC of the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

491. (Previously Presented) The method of claim 136, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

492. (Currently Amended) The method of claim 136, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of

the  $T_{\max}$  exhibited by micronized ~~feneffibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

493. (Previously Presented) The method of claim 136, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

494. (Previously Presented) The method of claim 136, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

495. (Previously Presented) The method of claim 136, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

496. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

497. (Previously Presented) The method of claim 136, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and

(c) within about 20 minutes about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

498. (Currently Amended) The method of claim 194, wherein the difference in AUC of the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, about 10%, about 5%, and about 3%.

499. (Previously Presented) The method of claim 194, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

500. (Currently Amended) The method of claim 194, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

501. (Previously Presented) The method of claim 194, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M,

and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

502. (Previously Presented) The method of claim 194, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

503. (Previously Presented) The method of claim 194, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

504. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

505. (Previously Presented) The method of claim 194, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

506. (Currently Amended) The method of claim 249, wherein the difference in AUC of the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of about 35%, about 30%, about 25%, about 20%, about 15%, less about 10%, about 5%, and about 3%.

507. (Previously Presented) The method of claim 249, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of about 6 hours, about 5 hours, about 4 hours, about 3 hours, about 2 hours, about 1 hour, and about 30 minutes.

508. (Currently Amended) The method of claim 249, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{max}$  selected from the group consisting of about 90%, about 80%, about 70%, about 50%, about 30%, and about 25% of the  $T_{max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

509. (Previously Presented) The method of claim 249, wherein within about 5 minutes about 20%, about 30%, or about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

510. (Previously Presented) The method of claim 249, wherein within about 10 minutes about 40%, about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising

sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

511. (Previously Presented) The method of claim 249, wherein within about 20 minutes about 70%, about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

512. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes about 30% of the composition is dissolved;
- (b) within about 10 minutes about 70% of the composition is dissolved; and
- (c) within about 20 minutes about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

513. (Previously Presented) The method of claim 249, wherein:

- (a) within about 5 minutes about 40% of the composition is dissolved;
- (b) within about 10 minutes about 80% of the composition is dissolved; and
- (c) within about 20 minutes about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

514. (Currently Amended) The method of claim 304, wherein the difference in AUC of the ~~fenofibrate~~ (2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester) or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

515. (Previously Presented) The method of claim 304, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

516. (Currently Amended) The method of claim 304, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and less than 25% of the  $T_{\max}$  exhibited by micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

517. (Previously Presented) The method of claim 304, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

518. (Previously Presented) The method of claim 304, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

519. (Previously Presented) The method of claim 304, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium



lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

520. (Previously Presented) The method of claim 304, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

521. (Previously Presented) The method of claim 304, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;
- (b) within about 10 minutes at least 80% of the composition is dissolved; and
- (c) within about 20 minutes at least 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

522. (Currently Amended) The method of claim 358, wherein the difference in AUC of the fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

523. (Previously Presented) The method of claim 358, wherein the composition exhibits a  $T_{max}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

524. (Currently Amended) The method of claim 358, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-

methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and less than 25% of the  $T_{\max}$  exhibited by micronized fenofibrate 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

525. (Previously Presented) The method of claim 358, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

526. (Previously Presented) The method of claim 358, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

527. (Previously Presented) The method of claim 358, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

528. (Previously Presented) The method of claim 358, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

529. (Previously Presented) The method of claim 358, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;
- (b) within about 10 minutes at least 80% of the composition is dissolved; and
- (c) within about 20 minutes at least 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

530. (Currently Amended) The method of claim 412, wherein the difference in AUC of the ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than 35%, less than 30%, less than 25%, less than 20%, less than 15%, less than 10%, less than 5%, and less than 3%.

531. (Previously Presented) The method of claim 412, wherein the composition exhibits a  $T_{\max}$  after administration to fasting human subjects selected from the group consisting of less than 6 hours, less than 5 hours, less than 4 hours, less than 3 hours, less than 2 hours, less than 1 hour, and less than 30 minutes.

532. (Currently Amended) The method of claim 412, wherein in comparative pharmacokinetic testing with a micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 160 mg tablet or micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof 200 mg capsule, which are standard commercial formulations of microcrystalline ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof, the composition exhibits a  $T_{\max}$  selected from the group consisting of less than 90%, less than 80%, less than 70%, less than 50%, less than 30%, and

less than 25% of the  $T_{\max}$  exhibited by micronized ~~fenofibrate~~ 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester or a salt thereof tablet or capsule.

533. (Previously Presented) The method of claim 412, wherein within about 5 minutes at least 20%, at least 30%, or at least 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

534. (Previously Presented) The method of claim 412, wherein within about 10 minutes at least 40%, at least 50%, at least 60%, at least 70%, or at least 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

535. (Previously Presented) The method of claim 412, wherein within about 20 minutes at least 70%, at least 80%, at least 90%, or at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

536. (Previously Presented) The method of claim 412, wherein:

- (a) within about 5 minutes at least 30% of the composition is dissolved;
- (b) within about 10 minutes at least 70% of the composition is dissolved; and
- (c) within about 20 minutes at least 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

537. (Previously Presented) The method of claim 412, wherein:

- (a) within about 5 minutes at least 40% of the composition is dissolved;
- (b) within about 10 minutes at least 80% of the composition is dissolved; and

(c) within about 20 minutes at least 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.